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Frudakis and Shriver
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Filed: August 19, 2003
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Attorney Docket No.: DNA1170-2

REMARKS

Claims 2, 4, 7, 10-23, 25-28, 33-36, 38, 46, and 59-82 have been canceled without prejudice or disclaimer. Claims 1, 5, 6, 8,-24, 31, 37, 39-43, 45, 49-51, 53, and 56 have been amended. Subsequent to the entry of the present amendment, claims 1, 3, 5, 6, 8, 9, 24, 29-32, 37, 39-45, and 47-58 are pending and at issue. These amendments and additions add no new matter as the claim language is fully supported by the specification and original claims.

I. Interview Summary

Applicants' representative gratefully acknowledges the careful consideration of the application and helpful suggestions made by Examiner Marina Miller and Primary Marjorie Examiner Moran in the telephone interview held on December 18, 2006. During the interview, proposed responses to the rejection and amendments to the claims were discussed. Agreement was reached that:

1. Amending claim 1 to recite "contacting a sample comprising nucleic acid molecules of the test individual with hybridizing oligonucleotides wherein the contacting detects nucleotide occurrences of single nucleotide polymorphisms in a panel of at least about ten ancestry informative markers" would overcome the outstanding 35 U.S.C. §101 rejections;
2. Amending claims 1 and 31 to replace "wherein the nucleotide occurrences of the SNPs are indicative of a population structure" with "wherein the AIMSs are indicative of a population structure" would overcome the 35 U.S.C. §112, first paragraph (new matter) rejections;

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3. Cancelling claim 4 and amending claims 1 and 31, to recite "a panel of ancestry informative markers (AIMs), wherein the panel comprises at least about ten AIMS selected from SEQ ID NOs:1 to 331" and corresponding amendments to the dependent claims including deletion of the phrase "or combinations thereof," would overcome the 35 U.S.C. §112, first paragraph enablement rejections, and 35 U.S.C. §112, second paragraph indefiniteness rejections (as applied to these limitations), and 35 U.S.C. §103 rejections;

4. Amending the second occurrence of "a trait" in claim 1 to "the trait" would overcome the 35 U.S.C. §112, second paragraph indefiniteness rejection of this claim term;

5. Deleting the phrase "thereby inferring the trait of the individual" from claim 1 and "thereby estimating proportional ancestry of the individual" from claim 31 would overcome 35 U.S.C. §112, second paragraph rejection of these claims and the claims which depend therefrom;

6. Deleting the word "with" in claim 24 would overcome the 35 U.S.C. §112, second paragraph rejection;

In addition, the 35 U.S.C. §112, second paragraph rejection was overcome by the explanation that the term "linked" in claims 1 and 31 refers to genetic linkage, a term of art that would be understood by the skilled artisan in view of the claims and specification.

Applicants agreed to submit an amendment and response to the final office action consistent with the amendments discussed during the telephone interview, which should place the application in condition for allowance.

II. Amendment to the Claims

Claims 1 and 31 have been amended to replace “detecting ...occurrences of single nucleotide polymorphisms..” with “contacting a sample comprising nucleic acid molecules of the individual with hybridizing oligonucleotides wherein said contacting detects nucleotide occurrences of single nucleotide polymorphisms (SNPs) in a panel of ancestry informative markers...” Support for these amendments can be found, e.g., in the original claims as filed and in the specification, particularly at [0012], [0024], and [0079]-[0088] describing a variety of methods for detecting single nucleotide polymorphisms that are suitable for use in the methods of the invention, all of which involve a oligonucleotide contacting step. Therefore, this amendment adds no new matter.

Claims 1 and 31 have also been amended to incorporate the limitations of claim 4 (now cancelled). As such, no new matter has been added by way of these amendments.

Claim 1 has also been amended to clarify the antecedent basis for “trait of the individual.” This amendment corrects a technical error and as such adds no new matter.

Claims 1 and 31, step a) have been amended to clarify that the AIMs are indicative of a population structure. Support for this amendment can be found, for example, in the claims as filed. In addition, step b)of claims 1 and 31, has been amended for clarity to refer to “the nucleotide occurrences of the AIMs detected in the individual of step a)” and references to nucleotide occurrences in dependent claims (24, 39, 40, 41, 42, 45, 50) have been amended to

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conform to this language. Support for these amendments can be found, for example, in the original claims as filed.

In the same context, claims 50, 51, 53, 56 have been amended to specify “AIMs indicative of BGA,” consistent with claim 58 and with the original claims as filed. In addition, occurrences of “the test individual” in claims 45, 49, and 58 have been amended to “the individual,” consistent with the antecedent “an individual” in independent claim 31. As such, these amendments are of a technical nature and therefore add no new matter.

Claim 5 has been amended to clarify that the panel of AIMs (which comprises “at least about ten” AIMs), are selected from SEQ ID NOS:1 to 71. Support for this claim amendment can be found in the original claims as filed and in the specification at, e.g., [0014], [0026], [0032], [0039], [0067], [0131], [0155], [0168], and [0182]. As such, this amendment adds no new matter.

Claims 6 and 37 have been amended to more clearly state that the panel of AIMs comprises the recited sequences, and to eliminate the phrase “and combinations thereof.” This amendment is of a technical nature and as such adds no new matter.

Claim 24 has been amended to correct a typographical error by deleting the word “with.” This amendment thus corrects a technical error and as such adds no new matter.

Claim 45 has been amended to more clearly recite the steps that are added to this dependent claim in order that ethnicity is identified as well as ancestry is estimated. The

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language of the steps was modeled after language of claim 31 and are fully supported by the specification, for example at [0019], [0031], and [0032].

Claims 8 and 43 have also been amended to replace "said" with "the." This is a technical amendment having no affect on subject matter of the claim. As such, no new matter has been added.

III. Restriction Requirement

Applicants acknowledge with thanks the Examiner's reconsideration of the election of species requirement and claim rejoinder in view thereof. Office Action at p. 2.

Regarding the restriction requirement, Applicants have cancelled previously withdrawn claims 12, 15-16, and 21-22. Applicants reserve the right to pursue the subject matter of cancelled claims 12, 15-16, and 21-22 in one or more divisional or continuing applications.

IV. Objections to the Claims

Claims 12, 15-16, and 21-22 have been objected to because of the alleged informality that the claims were withdrawn in the Office Action mailed September 22, 2005, but were incorrectly identified as "original" in the response dated August 14, 2006. Office Action at p. 2.

Applicants submit that the objection is moot in view of the cancellation of claims 12, 15-16, and 21-22. Applicants submit that the status of all claims listed on the Listing of Claims (p. 2 above) are correctly identified.

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Accordingly, reconsideration and withdrawal of the objection to claims 12, 15-16, and 21-22 is respectfully requested.

V. Information Disclosure Statement

Applicants acknowledge with thanks the returned initialed Form PTO 1449, which was filed August 14, 2006.

VI. Rejection under 35 USC § 101 (Non-statutory subject matter)

Claims 1, 3-6, 8-9, 24, 29-32, 37, 39-45, and 47-58 have been rejected under 35 U.S.C. §101 because the claimed invention is allegedly directed to non-statutory subject matter.

According to the Examiner, the claimed method does not transform or reduce an article or a physical object (*e.g.*, a molecule, a sample, a signal produced by labels, *etc.*) to a different stage or thing.” Office Action at 3.

Applicants submit that the rejection is moot in view of the amendments to claims 1 and 31, which specify that the detecting step is “contacting a sample comprising nucleic acid molecules of the individual with hybridizing oligonucleotides wherein said contacting detects detecting, in a nucleic acid sample from an individual, nucleotide occurrences of single nucleotide polymorphisms.”

Accordingly, reconsideration and withdrawal of the rejection of claims 1, 3-6, 8-9, 24, 29-32, 37, 39-45, and 47-58 is respectfully requested.

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VII. Rejections under 35 U.S.C. §112, First Paragraph (Written Description)

Claims 1, 3-6, 8-9, 24, 29-32, 37, 39-45, and 47-58 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Office Action at p. 4. Specifically, the Examiner states that the rejected claims “recite that SNPs detected in a sample from an individual are indicative of a population structure, but the phrase ‘does not have support in the specification, claims, or drawings, as originally filed.’” Id. at 5.

Applicants submit that the rejection is moot in view of the amendments to independent claims 1 and 31 replacing the phrase “wherein the nucleotide occurrences of the SNPs are indicative of a population structure” with “wherein the AIMSs are indicative of a population structure;” and the amendment of step b) in claims 1 and 31 to recite “identifying the population structure indicated by the nucleotide occurrences of the AIMs detected in the individual of step a).” Conforming amendments have also been made to claims which dependent from claims 1 or 31.

Accordingly, reconsideration and withdrawal of the rejection of claims 1, 3-6, 8-9, 24, 29-32, 37, 39-45, and 47-58 under 35 U.S.C. §112, first paragraph, is respectfully requested.

VIII. Rejections under 35 U.S.C. §112, First Paragraph (Enablement)

Claims 1, 3-6, 8-9, 24, 29-32, 37, 39-45, and 47-58 have been rejected under 35 U.S.C. §112, first paragraph, because the specification allegedly “does not reasonably provide enablement for an AIM panel of unknown specificity.” Office Action at 6.

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The Examiner acknowledges, however, the specification is “enabling for specific AIM panels disclosed in the specification {e.g., in tables 1-3 and 6) and recited in the instant claims (claims 4-6 and 37).” Id.

Applicants submit that the rejection is moot in view of the cancellation of claim 4 and the amendments to incorporate the limitation of cancelled claim 4 into claims 1 and 31, because the Examiner found dependent claim 4 to be enabled by the specification.

Accordingly, reconsideration and withdrawal of the rejection of claims 1, 3-6, 8-9, 24, 29-32, 37, 39-45, and 47-58 under 35 U.S.C. §112, first paragraph is respectfully requested.

IX. Rejections under 35 U.S.C. §112, Second Paragraph (Indefiniteness)

The Office Action states that “claims are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” Office Action at 8.

Applicants address the specific grounds of rejection in the order in which they are stated in the Office Action.

1. Claims 1, 3-6, 8, 24, and 29-30

The Office Action states that “[c]laim 1, as amended, recites ‘a trait’ in line 9. Claim 1 also recites ‘a trait’ in line 2. It is not clear whether ‘a trait’ recited in lines 2 and 9 are the same or different. Claim 1 also recites “the trait” in lines 17 and 18.” Office Action at p. 8. According

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to the Examiner, it is not clear which trait is referred to in claim, lines 17 and 18, and dependent claims 3-6, 8, 24 and 29-30. Id. 8-9.

Claim 1 has been amended to recite “the trait” at the second occurrence of “trait” (line 9 in the Amendment filed August 14, 2006). Applicants submit that the rejection of claims 1, 3-6, 8, 24, and 29-30 is moot in view of the amendment to claim 1.

Accordingly, reconsideration and withdrawal of the rejection of claims 1, 3-6, 8, 24, and 29-30 under 35 U.S.C. §112, first paragraph is respectfully requested.

2. Claims 1, 3-6, 8, 24, and 29-30

The Office Action states “[c]laim 1, as amended, recites in the preamble ‘a method of inferring.’” Office Action at 9. According to the Examiner [i]t is not clear whether the limitations ‘wherein identifying the population structure infers the trait’ and/or ‘thereby inferring the trait’ are intended to be an active, positive step(s) of the method, or merely an intended use of the identified population structure.” Id. “As the intended limitation is not clear, claims 1, 3-6, 8, 24, and 29-30 are indefinite.” Id.

Applicants submit that the rejection of claims 1, 3-6, 8, 24, and 29-30 as indefinite is moot in view of the amendments to claim 1, deleting the phrase “thereby inferring the trait of the individual.”

Accordingly, reconsideration and withdrawal of the rejection of claims 1, 3-6, 8, 24, and 29-30 under 35 U.S.C. §112, second paragraph, is respectfully requested.

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3. Claims 1, 3-6, 8, 24, and 29-30

The Office Action states “[c]laim 1, as amended, recites in step (a) detecting SNPs in a panel of AIMs, wherein SNPs are indicative of a population structure. Claim 1 further recites in step (b) identifying the repopulation structure indicated by SNPs detected in step (a). It is not clear what limitation is intended by reciting step (b) because the step is redundant, i.e., SNPs indicative of the population structure has been identified in step (a). As the intended limitation is not clear, claims 1, 3-6, 8, 24, and 29-30 are indefinite.”

Applicants submit that the rejections of claims 1, 3-6, 8, 24, and 29-30 are moot in view of the amendments to claim 1 to specify the steps:

- a) contacting a sample comprising nucleic acid molecules of the individual with hybridizing oligonucleotides wherein said contacting detects nucleotide occurrences of single nucleotide polymorphisms (SNPs) in a panel of ancestry informative markers (AIMs), wherein the panel comprises at least about ten AIMS selected from SEQ ID NOS:1 to 331, wherein the AIMs are indicative of a population structure, wherein the population structure is correlated with the trait of the individual, and wherein the panel comprises at least one AIM that is not linked to a gene linked to the trait; and
- b) identifying the population structure indicated by the nucleotide occurrences of the AIMs detected in the individual of step a), wherein identifying the population structure infers the trait.

Accordingly, reconsideration and withdrawal of the rejection of claims 1, 3-6, 8, 24, and 29-30 under 35 U.S.C. §112, second paragraph, is respectfully requested.

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4. Claims 1, 3-6, 8-9, 24, 29-32, 37, 39-45, and 47-58

The Office Action states that claims 1 and 31, are allegedly indefinite in the recitation of “linked” because it is not clear what linked means in view of the recitation of “correlated” in the same claims.” Office Action at p. 10.

Applicants submit that the term “linked” refers to genetic linkage, a term of art relating to the physical distance between genetic loci. The terms “linked,” “unlinked” “genetically linked” and the like are used throughout the specification to refer loci that are in close proximity. See for example, paragraphs [0006] [0007], [0014], [0065], [0097], [0099] and [0102], among others. Applicants further submit that the skilled artisan would understand the meaning of the word “linked” in the context of whether a marker was linked to a trait, as recited in claims 1 and 31.

Accordingly, reconsideration and withdrawal of the rejection of claims 1, 3-6, 8, 24, and 29-30 under 35 U.S.C. §112, second paragraph, is respectfully requested.

5. Claims 4-6

According to the Examiner, claims 4-6 “recite the limitation ‘wherein the panel comprises AIMs set forth as’ SEQ ID NOs:1 to 331, 1 to 71, and three panels of various SEQ ID NOs. Office Action at 10. “It is not clear whether a panel [as recited in claims 4-6] comprises all the recited SEQ ID NOs or a subset thereof. As the intended limitation is not clear, claims 4-6 are indefinite.” Id.

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Applicants submit that the rejection is moot in view of the amendments to the claims.

Claim 4 has been cancelled and claim 1 has been amended to incorporate the limitations of now-cancelled claim 4. Specifically, claim 1 specifies "a panel of ancestry informative markers (AIMs), wherein the panel comprises at least about ten AIMS selected from SEQ ID NOs:1 to 331." Dependent claims 5 and 6 have been amended in a similar fashion to indicate panels comprising subsets of the AIMs of claim 1.

Accordingly, reconsideration and withdrawal of the rejection of claims 4-6 under 35 U.S.C. §112, second paragraph, is respectfully requested.

6. Claims 24

The Office Action states "[c]laim 24, as amended, recites the limitation 'wherein the sub-population structure infers with the trait.' It is not clear what limitation is intended." Office Action at 10.

Applicants submit that the rejection is moot in view of the amendment of claim 24 to delete the word "with."

Accordingly, reconsideration and withdrawal of the rejection of claim 24 under 35 U.S.C. §112, second paragraph, is respectfully requested.

7. Claims 31-32, 37, 39-45, and 47-58

The Office Action states "[c]laim 31, as amended, recites in the preamble "a method of estimating." The claim further recites steps of detecting SNPs and identifying population the

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structure, "wherein identifying the population structure estimates proportional ancestry, thereby estimating proportional ancestry." It is not clear whether the limitations "wherein identifying the population structure estimates proportional ancestry" and/or "thereby estimating proportional ancestry" are intended to be an active, positive step(s) of the method, or merely an intended use of the identified population structure. Further, because it is not clear whether the method comprises an active positive step of "estimating proportional ancestry," the relation between the preamble and the method steps is still not clear." Office Action at p. 11. "As the intended limitation is not clear, claims 31-32, 37, 39-45, and 47-58 are indefinite." Id.

Applicants submit that the rejection is moot in view of the amendment to claim 31 to delete the phrase "thereby estimating proportional ancestry."

Accordingly, reconsideration and withdrawal of the rejection of claim 31 under 35 U.S.C. §112, second paragraph, is respectfully requested.

8. Claims 45 and 47

The Office Action states "[c]laim 45, as amended, recites the limitation 'wherein the sub-population structure infers ethnicity of the test individual.' It is unclear whether the limitation 'wherein the sub-population structure infers' is intended to be an active, positive step(s) of the method, or merely an intended use of the identified sub-population structure. It is further unclear what steps, algorithms, or models are used for 'inferring.' Further, claim 45 depends from claim 31 which is directed to a method of estimating proportional ancestry comprising steps of

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detecting SNPs and identifying the population structure wherein the structure estimates proportional ancestry. It is not clear where "inferring ethnicity" recited in claim 45 fits within the steps of claim 31. As the intended limitation is not clear, claims 45 and 47 are indefinite." Office Action at p. 12.

Applicants submit that the rejection is moot in view of the amendments to claim 45 clarifying that the claim further comprises identifying an ethnicity of the individual, and that the AIMs are also indicative of a sub-population structure. The amendments to claim 45 have been drafted to echo the steps of claim 31, in a manner consistent with the amendments made in order to overcome a similar rejection to that claim.

Accordingly, reconsideration and withdrawal of the rejection of claims 45 and 47 under 35 U.S.C. §112, second paragraph, is respectfully requested.

VI. Rejections under 35 U.S.C. § 103

Claims 1, 3, 8, and 31-32 stand rejected under 35 U.S.C. 103(a) as allegedly unpatentable over McKeigue, *Ann. Hum. Genet.*, 64:171-186 (2000), in view Hanis, *Am. J. Physical Anthropol.*, 70:433-441 (1986).

Claims 1, 3, 8, 31-32, and 39 stand rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Parra, *Am. J. Physical Anthropol.*, 114-118 (2001), in view Hanis, *Am. J. Physical Anthropol.*, 70:433-441 (1986).

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Claims 1, 3, 8, 24, 30-32, 45, and 50-52 stand rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Sorenson, US 2003/0172065, in view of Hanis, *Am. J. Physical Anthropol.*, 70:433-441 (1986).

Claim 9 stands rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Sorenson, US 2003/0172065, in view of Hanis, *Am. J. Physical Anthropol.*, 70:433-441 (1986), as applied to claims 1, 3, 8-9, 24, 30-32, 45, and 50-52 above, in view of Collins-Schramm, *Am. J. Hum. Genet.*, 70:737-750 (2/11/2002), and further in view of Kanetsky, *Am. J. Hum. Genet.*, 70:770-775 (2/6/2002).

Claims 29 stands rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Sorenson, US 2003/0172065, in view of Hanis, *Am. J. Physical Anthropol.*, 70:433-441 (1986), as applied to claims 1, 3, 8-9, 24, 30-32, 45, and 50-52 above, in view of Akey, *BioTechnique*, 30(2):358-367 (2001).

Claims 40-43 stand rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Parra, *Am. J. Physical Anthropol.*, 114-118 (2001), in view of Hanis, *Am. J. Physical Anthropol.*, 70:433-441 (1986), as applied to claims 1, 3, 8-9, 31-32, and 39 above, in view of Pritchard, *Theoretical Population Biology*, 60:227-237 (2001).

Claim 48 stands rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Sorenson, US 2003/0172065, in view of Hanis, *Am. J. Physical Anthropol.*, 70:433-441 (1986), as applied to claims 1, 3, 8-9, 24, 30-32, 45, and 50-52 above, in view of Pritchard, *Genetics*, 155:945-959 (2000).

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Applicants respectfully disagree with the Examiner's conclusions regarding the obviousness of the claimed methods in view of the cited art. Nevertheless, without acquiescing to the validity of the rejection under 35 U.S.C. §103(a), and in an effort to advance prosecution, Applicants note that claim 4 has not been rejected under this statute.

Applicant's further note that independent claims 1 and claims 31 have been amended to incorporate the limitations of claim 4, and claim 4 has been cancelled in an effort to overcome the enablement rejection set forth above in section VIII.

Applicants submit that the rejections under 35 U.S.C. §103(a) are moot in view of the amendments to claims 1 and 31.

Accordingly, reconsideration and withdrawal of rejection of claims 1, 3, 8, 9, 24, 29-32, 39, 40-43, 45, and 50-52 under 35 U.S.C. §103, is respectfully requested.

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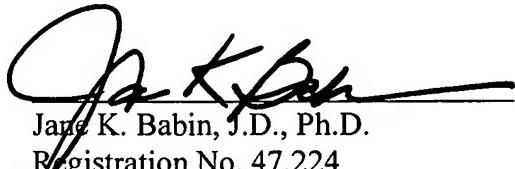
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Conclusion

In view of the foregoing amendments and remarks, Applicants submit that the claims are in condition for allowance, and a notice to that effect is respectfully requested. The Examiner is invited to contact Applicant's undersigned representative if there are any questions relating to this application.

No fee is believed necessary with the filing of this paper. However, the Commissioner is hereby authorized to charge any fees that are required, or credit any overpayments to Deposit Account No. 07-1896 referencing the above-identified attorney docket number. A copy of the Transmittal Sheet is enclosed.

Respectfully submitted,


Jane K. Babin, J.D., Ph.D.
Registration No. 47,224
Telephone: (858) 636-6638
Facsimile: (858) 677-1465

DLA PIPER US LLP
4365 Executive Drive, Suite 1100
San Diego, California 92121-2133
USPTO Customer No. 28213